

REMARKS

Rejection under 35 USC 102(e) - Shahidi (US 6,167,296)

1. Examiner rejected claims 1-4, 20, 24, 67-71 and 73-77 under 35 USC 102(e) as being anticipated by Shahidi (US 6,167,296).
2. Claims 1-4, 20, 24, 67-71 and 73-75 are novel and nonobvious over Shahidi by recitation of the following feature:

“wherein the location data consists of real-time data collected by the location means”

As has been discussed in prior responses, Shahidi:

“provides an improved system and method for displaying 3D images of anatomical structures in real time during surgery to enable the surgeon to navigate through these structures during the performance of surgical procedures. This system is also useful in planning of surgical procedures. The system includes a computer with a display and input devices such as a keyboard and mouse. The system includes a position tracking system that is connected both to the computer and also to the surgical probes or other instruments that are used by the surgeon. The position tracking system provides continual real time data to the computer indicating the location and orientation of the surgical instrument in use. The computer further includes a memory containing patient data produced by imaging scans, such as CT or MRI scans, from which 2-dimensional and 3-dimensional images of the anatomical structure may be generated. Means are provided for registration of these images with respect to the patient.” (Column 3, lines 22-39)

“In addition, for probes or instruments being used that are capable themselves of generating images, such as ultrasound probes, endoscopes, or surgical microscopes, the system provides means for integrating these images with those generated from the scan data. The software enables the user to overlay the ‘actual images’ generated by these instruments with the ‘virtual images’ generated from the scan data.” (Column 4, lines 6-13)

Shahidi uses stored patient image data to provide surgical guidance. A significant drawback to this situation is that the guidance relies upon the stored image data remaining accurate during surgery. For surgical targets involving hard tissues such as bone and cartilage, this

method has obvious applicability, for example in neurosurgery or orthopedic surgery. However, Applicant's invention is used in the eye which is a relatively soft structure, whose size and shape relates to the intraocular pressure and forces being applied directly during surgery. Variations in the patient's intraocular pressure, the use of a protective paracentesis to remove intraocular pressure during eye surgery, and the force applied to the eye by the imaging means or the microsurgical device can change the size and shape of the anterior segment angle containing Schlemm's Canal by several millimeters. Since Schlemm's Canal is a tissue structure of approximately 150 microns in diameter, such lack of accuracy of potentially thousands of microns from the stored image data would be ineffective in guiding a microcannula to Schlemm's Canal by using any type of stored data as is used in Shahidi.

Applicant's claimed configuration uses *only* the real time data generated by the locating means. Since Shahidi does not disclose a device that could be used to locate and advance a microsurgical device into Schlemm's Canal using only real-time data as recited in claims 1-4, 20, 24, 67-71 and 73-75, Applicant respectfully submits that the claims, as amended, overcome the rejection under 102(e).

Rejection under 35 USC 103(a) - Shahidi (US 6,167,296) in view of Thomas III et al (US 4,911,170)

3. Examiner rejected claim 6 and 7 under 35 USC 103(a) as being unpatentable over Shahidi in view of Thomas III et al. (US 4,911,170).
4. Thomas III et al. discloses a typical side-imaging catheter used in cardiology. Once inserted into an artery, the imaging system is used to create ultrasonic images of the artery and plaque. The side imaging is not suitable for guidance of the catheter. As such, it would not be capable of non-invasively locating Schlemm's Canal and advancing a microsurgical device therein using only the data collected by the locating means as is recited in claim 1, from which claims 6 and 7 depend.

Furthermore, Thomas III et al. would not be capable of providing either the 3D images or the forward directed images used in Shahidi. Therefore, Applicant submits that it would be counter to the teaching of Shahidi to use the catheter of Thomas III et al. And even if the two were combined, it would fail to disclose Applicant's claimed configuration which uses *only* the real time data generated by the locating means.

Shahidi, Thomas III et al. or any combination thereof do not disclose or suggest a device that could be used to locate and advance a microsurgical device into Schlemm's Canal using only real-time data as recited in claims 6 and 7, Applicant respectfully submits that the claims, as amended, overcome the rejection under 103(a) and respectfully requests allowance of these claims.

Rejection under 35 USC 103(a) - Shahidi (US 6,167,296) in view of Bernstein (US6,132,699)

5. Examiner rejected claim 8 under 35 USC 103(a) as being unpatentable over Shahidi in view of Bernstein (6,132,699).
6. Bernstein discloses the use of contrast agents for ultrasound imaging. It does not disclose a device capable of non-invasively locating Schlemm's Canal and advancing a microsurgical device therein using only the data collected by the locating means as is recited in claim 1, from which claim 8 depends. Even if the contrast agent of Bernstein were added to the system of Shahidi, it would fail to disclose Applicant's claimed configuration.

Shahidi, Bernstein or any combination thereof do not disclose or suggest a device that could be used to locate and advance a microsurgical device into Schlemm's Canal using only real-time data. Therefore, Applicant submits that claim 8 is novel and nonobvious over the prior art and respectfully request allowance of this claim.

Rejection under 35 USC 103(a) - Shahidi (US 6,167,296) in view of LeBlanc et al. (5,989,189)

7. Examiner rejected claim 10 under 35 USC 103(a) as being unpatentable over Shahidi in view of LeBlanc et al. (5,989,189).
8. LeBlanc et al. discloses color mapping to allow the view to improve image presentation and to better discriminate the large structures of the eye, such as the cornea, retina, etc. It does not disclose a device capable of non-invasively locating Schlemm's Canal and advancing a microsurgical device therein using only the data collected by the locating means as is recited in claim 1, from which claim 10 depends. Even if the contrast agent of LeBlanc et al. were added to the system of Shahidi, it would fail to disclose Applicant's claimed configuration.

Shahidi, LeBlanc et al. or any combination thereof do not disclose or suggest a device that could be used to locate and advance a microsurgical device into Schlemm's Canal using only real-time data. Therefore, Applicant submits that claim 10 is novel and nonobvious over the prior art and respectfully request allowance of this claim.

Rejection under 35 USC 103(a) - Shahidi (US 6,167,296) in view of Schachar (6,146,366)

9. Examiner rejected claim 18 under 35 USC 103(a) as being unpatentable over Shahidi in view of Schachar (6,146,366).
10. Schachar discloses a device to be implanted into scleral tissues in the posterior region of the eye to alter the shape of the eye. It does not disclose a device capable of non-invasively locating Schlemm's Canal and advancing a microsurgical device therein using only the data collected by the locating means as is recited in claim 1, from which claim 18 depends. Even if the implant of Schachar were added to the system of Shahidi, it would fail to disclose Applicant's claimed configuration.

Shahidi, Schachar or any combination thereof do not disclose or suggest a device that could

be used to locate and advance a microsurgical device into Schlemm's Canal using only real-time data. Therefore, Applicant submits that claim 18 is novel and nonobvious over the prior art and respectfully request allowance of this claim.

Rejection under 35 USC 103(a) - Shahidi (US 6,167,296) in view of Steen et al. (5,984,904)

11. Examiner rejected claims 19, 27- 29, 31 and 46 under 35 USC 103(a) as being unpatentable over Shahidi in view of Steen et al. (5,984,904).
12. Steen et al. discloses a surgical instrument having a cutting tip for removing the natural lens from the eye. It does not disclose a device capable of non-invasively locating Schlemm's Canal and advancing a microsurgical device therein using only the data collected by the locating means as is recited in the independent claims from which these claims depend. Even if the surgical instrument of Steen et al. were added to the system of Shahidi, it would fail to disclose Applicant's claimed configuration.

Shahidi, Steen et al. or any combination thereof do not disclose or suggest a device that could be used to locate and advance a microsurgical device into Schlemm's Canal using only real-time data. Therefore, Applicant submits that claims 19, 27- 29, 31 and 46 are novel and nonobvious over the prior art and respectfully request allowance of these claims.

Rejection under 35 USC 103(a) - Shahidi (US 6,167,296)

13. Examiner rejected claim 21 under 35 USC 103(a) as being unpatentable over Shahidi.
14. As discussed above Shahidi does not disclose or suggest a device capable of non-invasively locating Schlemm's Canal and advancing a microsurgical device therein using only the data collected by the locating means as is recited in the independent claims from which this claim depends. Therefore, Applicant submits that claims 21 is novel and nonobvious over the prior art and respectfully request allowance of this claim.

Rejection under 35 USC 103(a) - Shahidi (US 6,167,296) in view of Imling et al. (6,203,499)

15. Examiner rejected claims 22 and 23 under 35 USC 103(a) as being unpatentable over Shahidi in view of Imling et al. (6,203,499).
16. Imling et al. discloses a needle guide that positions a biopsy needle in the scan plan of an ultrasonic imaging probe. It does not disclose a device capable of non-invasively locating Schlemm's Canal and advancing a microsurgical device therein using only the data collected by the locating means as is recited in the independent claims from which these claims depend. Even if the guide of Imling et al. were added to the system of Shahidi, it would fail to disclose Applicant's claimed configuration.

Shahidi, Imling et al. or any combination thereof do not disclose or suggest a device that could be used to locate and advance a microsurgical device into Schlemm's Canal using only real-time data. Therefore, Applicant submits that claims 22 and 23 are novel and nonobvious over the prior art and respectfully request allowance of these claims.

Rejection under 35 USC 103(a) - Shahidi (US 6,167,296) in view of Simon (4,883,053)

17. Examiner rejected claim 25 under 35 USC 103(a) as being unpatentable over Shahidi in view of Simon (4,883,053).
18. Simon discloses a biopsy needle guide or "angulator." It does not disclose a device capable of non-invasively locating Schlemm's Canal and advancing a microsurgical device therein using only the data collected by the locating means as is recited in the independent claims from which these claims depend. Even if the surgical instrument of Simon were added to the system of Shahidi, it would fail to disclose Applicant's claimed configuration.

Shahidi, Simon or any combination thereof do not disclose or suggest a device that could be

used to locate and advance a microsurgical device into Schlemm's Canal using only real-time data. Therefore, Applicant submits that claims 25 is novel and nonobvious over the prior art and respectfully request allowance of this claim.

Rejection under 35 USC 103(a) - Shahidi (US 6,167,296) in view of Mohr, Jr. et al. (5,921,954)

19. Examiner rejected claim 26 under 35 USC 103(a) as being unpatentable over Shahidi in view of Mohr, Jr. et al. (5,921,954).

20. Mohr Jr. et al. discloses a curved catheter. It does not disclose a device capable of non-invasively locating Schlemm's Canal and advancing a microsurgical device therein using only the data collected by the locating means as is recited in the independent claims from which these claims depend. Even if the surgical instrument of Steen et al. were added to the system of Shahidi, it would fail to disclose Applicant's claimed configuration.

Shahidi, Steen et al. or any combination thereof do not disclose or suggest a device that could be used to locate and advance a microsurgical device into Schlemm's Canal using only real-time data. Therefore, Applicant submits that claims 26 is novel and nonobvious over the prior art and respectfully request allowance of this claim.

Rejection under 35 USC 103(a) - Shahidi (US 6,167,296) in view of Lynch et al. (6,524,275)

21. Examiner rejected claims 32-34, 37, 38, 45 and 72 under 35 USC 103(a) as being unpatentable over Shahidi in view of Lynch et al. (6,524,275).

22. Lynch et al. discloses an inflatable device placed within Schlemm's Canal. However, it does not describe any means to accomplish this in a minimally invasive manner. It does not disclose a device capable of non-invasively locating Schlemm's Canal and advancing a microsurgical device therein using only the data collected by the locating means as is recited in the independent claims from which these claims depend. Even if the inflatable device of

Lynch et al. were added to the system of Shahidi, it would fail to disclose Applicant's claimed configuration.

Shahidi, Lynch et al. or any combination thereof do not disclose or suggest a device that could be used to locate and advance a microsurgical device into Schlemm's Canal using only real-time data. Therefore, Applicant submits that claims 32-34, 37, 38, 45 and 72 are novel and nonobvious over the prior art and respectfully request allowance of these claims.

Rejection under 35 USC 103(a) - Shahidi (US 6,167,296) in view of Lafont et al. (5,957,975)

23. Examiner rejected claims 39 and 42 under 35 USC 103(a) as being unpatentable over Shahidi in view of Lafont et al. (5,957,975).

24. Lafont et al. discloses the use of biodegradable vascular stents. It does not disclose a device capable of non-invasively locating Schlemm's Canal and advancing a microsurgical device therein using only the data collected by the locating means as is recited in the independent claims from which these claims depend. Even if the inflatable device of Lafont et al. were added to the system of Shahidi, it would fail to disclose Applicant's claimed configuration.

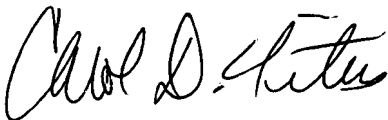
Shahidi, Lafont et al. or any combination thereof do not disclose or suggest a device that could be used to locate and advance a microsurgical device into Schlemm's Canal using only real-time data. Therefore, Applicant submits that claims 39 and 42 are novel and nonobvious over the prior art and respectfully request allowance of these claims.

CONCLUSION

For all the reasons above, Applicant submits that the claims all define novel subject matter that is nonobvious. Therefore, allowance of these claims is submitted to be proper and is respectfully requested.

Applicant invites the Examiner to contact Applicant's representative as listed below for a telephonic interview if so doing would expedite the prosecution of the application.

Very respectfully submitted,



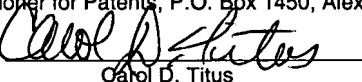
Carol D. Titus
GSS Law Group
3900 Newpark Mall Rd
Third Floor, Suite 317
Newark, CA 94560

Reg. No. 38,436
Phone (510) 742-7417
Fax (510) 742-7419

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Carol D. Titus

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